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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,706	09/11/2003	Simon L. McGurk	029318-0968	4753
31049	7590	10/20/2006	EXAMINER	
ELAN DRUG DELIVERY, INC. C/O FOLEY & LARDNER LLP 3000 K STREET, N.W. SUITE 500 WASHINGTON, DC 20007-5109			SILVERMAN, ERIC E	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/659,706	Applicant(s) MCGURK ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 23, 29 and 44-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-22, 24-28, 30-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant is advised that the Examiner assigned to this Application has changed. The Examiner currently assigned to this Application is **Eric Silverman, PhD**, whose contact information can be found at the end of this action. Applicant is further advised that this Application is currently assigned to **Art Unit 1615**.

Applicants' response, and amendment, filed 7/7/2006, have been received. Claims 1 – 46 are pending, and claims 9 – 11, 23, 29, and 44 – 46 are withdrawn as non-elected inventions or non-elected species, there being no allowable generic or linking claim(s).

It is noted that on the current listing of claims, filed 7/7/2006, claims 9 – 11, 23, and 29 are listed with the status identifier "original". This aspect of the claims listing is not correct; these claims are currently withdrawn. See also the office action mailed 4/10/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 8, 12 – 22, 24 – 28, and 30 – 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

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time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The amendment reciting "wherein the composition comprises at least about 5% by water, based on the total weight of the composition" is new matter. It is noted that Applicant points to paragraph 30 in the specification for support for this amendment. Paragraph 30 is reproduced below.

[0030] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the invention as claimed. Other objects, advantages, and novel features will be readily apparent to those skilled in the art from the following detailed description of the invention.

Clearly, this section of the specification does not provide support for the amendment. A careful review of the remainder of the originally filed disclosure also shows no support for the added subject matter. The amendment accordingly introduces new matter into the claims.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 – 8, 12 – 22, 24 – 28, 30 – 43 **remain** rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/18374 for reasons of record and those discussed above.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

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Applicant argues that the rate controlling polymers of the '374 application cannot be considered to be the "gel forming substance" of instant claims, because the intended purpose of these polymers are different. This is unpersuasive because the rate forming polymers of the prior art document have the ability to form gels, and thus meet all the claimed requirements in instant claims. The purpose of the material, as defined in the specification, is not a limitation that is properly incorporated into the claims. Although the claims are read in view of the specification, incorporation of limitations from the specification into the claims is not proper. Applicants further argue that the claims require "excess water" which results in fast release, whereas the prior art exhibits slow release. Again, this is not persuasive since the components of instant composition are the same as those in the prior art composition. Furthermore, the claims do not require "excess water", but, as amended, require 5% or more of water.

This newly added limitation is met in at least two ways by the prior art. First, claim 23 of the prior art teaches soft gelatin capsules. Such capsules are understood to inherently include at least 5% water, as opposed to hard gelatin capsules, which contain much less. Secondly, the dosage form of the prior art is understood to be an osmotic dosage form in at least one claimed embodiment (see claim 29). In an osmotic dosage form, upon administration water from enters the dosage form and the osmotic pressure caused thereby releases the active agent. Thus, at least at some point after administration, this embodiment of the prior art invention will necessarily contain at least 5% of water.

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Claims 1 – 8, 12 – 22, 24 – 28, and 30 – 33 **remain** rejected under 35

U.S.C. 102(b) as being anticipated by US 6,316,029 to Jain et al for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an excess of water) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

To the extent that Applicants' intended to argue that the composition of Jain does not have more than 5% water, as is now claimed, this would also not be persuasive. During the making of the compositions of Jain, the components are blended and 20 g of deionized water is added during the blending (Example 3). The water added is at least 5% of the total weight of the composition. At least during this blending procedure, the composition of Jain meets the newly added limitation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Eric E. Silverman, PhD
Art Unit 1615



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